the DBL report

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An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

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Highlights of Products Added via Special Authorization (SA)

■ **IMITREX** (sumatriptan) (GLA) - the 50 mg strength has been added via SA to accomodate patients who are unable to tolerate the 100 mg tablets. Please refer to the appropriate section of the AHWDBL for details.

■ **LOSEC** (omeprazole magnesium) (AZC)- the 10 mg sustained-release tablet has been added via SA to meet the needs of patients unable to tolerate the 20 mg tablets.

■ **ZOMETA** (zolendronic acid) (NOV) has been added via SA according to the following criteria: "For the treatment of tumor-induced hypercalcemia in patients with documented evidence of intolerance or lack of response to clodronate or pamidronate." Following consultation with experts, zoledronic acid appears to be a third line agent, most appropriately reserved for use in patients resistant to clodronate and pamidronate.

Changes in SA Criteria

■ **ACTOS** (pioglitazone) (LIL) - the SA criteria have been re-reviewed by the ECDET at the request of the manufacturer. Although data supporting safety and efficacy exist for pioglitazone in combination with sulfonylureas and metformin, to date, an indication for combination therapy has not been approved by the TPD (Therapeutic Products Directorate). As a consequence, the ECDET recommended that ACTOS continue to be reimbursed for monotherapy only and this is reflected in the SA criteria. Therefore, the criteria for coverage read as follows: "For the treatment of Type 2 diabetes mellitus in patients who are not adequately controlled by optimum doses or who are intolerant to metformin or sulfonylureas, or for whom these products are contraindicated. ACTOS will be considered for coverage only when used as monotherapy."

■ **EPREX** (epoetin alfa) (ORT) – the SA criteria for this product have been expanded to include coverage: "For the treatment of anemia of cancer in patients with low hemoglobin (<100 g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20 g/L per month, the dose of EPREX should be reduced by about 25%. If hemoglobin exceeds 120 g/L, therapy should be discontinued until hemoglobin falls below 100 g/L, at which time EPREX should be re-instituted at a dose 25% below the previous dose." It is the view of the ECDET that transfusion remains a less expensive option and affords patients the immediate benefits of treatment.
Please note that renewal requests may be considered if the patient's hemoglobin is <120 g/L while on EPREX.

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Highlights of Products Not Added

■ **ANDRODERM** (testosterone) (PAL) has not been added to the AHWDBL since clinical data failed to show a significant therapeutic benefit compared to other testosterone products currently listed. Even though ANDRODERM may produce more physiologic levels of testosterone, no difference in reducing symptoms of hypogonadism and sexual dysfunction was demonstrated when compared to IM testosterone enanthate.

FLUOROQUINOLONES

■ **AVELOX** (moxifloxacin hydrochloride) (YNO) and

■ **TEQUIN** (gatifloxacin) (BMS) - following consultation with Alberta Infectious Disease specialists, the ECDET agrees that there is a significant concern regarding non-judicious use of broad-spectrum fluoroquinolones. As a result, it was recommended that these agents not be added since no therapeutic or cost advantage was seen in listing these products.

Suggest a Topic

Requests for topics or information on reviewed drug products to appear in The DBL Report are welcome and can be forwarded to:

Scientific and Research Services
Clinical Drug Services and Evaluation
Alberta Blue Cross
10009 - 108 St.
Edmonton, AB T5J 3C5
Fax (780) 498-8384

New LCA Products Added

New interchangeable groupings have been established with the addition of the following first entry generic products:

Drug	Generic Brand	Innovator Brand	Date Added
Cimetidine (oral solution)	Apo-Cimetidine	Tagamet (oral liquid)*	August 1, 2001
Hydrocortisone valerate (cream and ointment)	Tarocort	Westcort	August 1, 2001
Gabapentin	Pms-Gabapentin	Neurontin	July 1, 2001**
Lisinopril (10 mg tablet)	Apo-Lisinopril	Prinivil, Zestril	August 1, 2001
Nefazodone hydrochloride	Apo-Nefazodone, Lin-Nefazodone	Serzone	July 1, 2001**
Zopiclone (5 mg tablet)	Pms-Zopiclone	Imovane	August 1, 2001

* Recently discontinued.

** Please note that the products Pms-Gabapentin, Apo-Nefazodone and Lin-Nefazodone were fast-tracked because of the substantial savings they will bring to the government-sponsored programs.

Highlights of Deferred Products

■ **ENBREL** (etanercept) (WAY) is the first of a new class of genetically engineered biologic response modifiers (TNF antagonists). At the present time ENBREL is indicated for use in rheumatoid arthritis (RA), however, a large number of clinical trials are on-going or have been completed for many different indications. The ECDET has deferred a recommendation on this product pending consultation with the rheumatology community and other stakeholders.

■ **RENAGEL** (sevelamer hydrochloride) (GZM) is an non-absorbed phosphate binder indicated for the control of hyperphosphatemia in end-stage renal disease patients on hemodialysis. Therapeutic advantage is anticipated for patients who cannot tolerate traditional calcium-containing phosphate binders or who cannot control their hyperphosphatemia. In addition to reducing serum phosphate and parathyroid hormone levels, beneficial effects on LDL cholesterol have been demonstrated. Consultations with nephrologists in Alberta are on-going to determine the exact place in therapy for RENAGEL.

■ **RILUTEK** (riluzole) (AVE) is the first agent indicated for use in amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease). Clinical data have shown that RILUTEK may extend survival and/or time to tracheotomy; however, functional status and symptoms are not affected by treatment. Because of a lack of data in terms of HRQOL (Health Related Quality Of Life), the ECDET has deferred a recommendation on this product pending consultation with specialists.

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